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7
8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA
10 SAN FRANCISCO DIVISION

11 ANIMAL LEGAL DEFENSE FUND,

12 Plaintiff;

13 v.

14 UNITED STATES FOOD AND DRUG
15 ADMINISTRATION,

16 Defendant.

Case No.

CV 12 437
COMPLAINT FOR INJUNCTIVE AND
DECLARATORY RELIEF UNDER THE
FREEDOM OF INFORMATION ACT,
5 U.S.C. § 552

Judge:

17
18 INTRODUCTION

19 1. The Animal Legal Defense Fund ("ALDF") brings this action for injunctive and
20 declaratory relief under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, to compel the
21 United States Food and Drug Administration ("FDA") to produce records without certain redactions.
22 ALDF requested records related to egg production in Texas for the purpose of protecting animal welfare
23 and public safety by monitoring unsanitary conditions associated with diseases like salmonella and bird
24 flu. The FDA produced records but redacted critical information from fields relating to hen population
25 and living conditions.

26 2. The FDA improperly asserted that this information was exempt as confidential or

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1 privileged commercial information pursuant to 5 U.S.C. § 552(b)(4) ("Exemption 4"). Commercial
2 information is only confidential or privileged if public release is likely to (1) "impair the government's
3 ability to obtain necessary information in the future" or (2) "cause potential harm to the competitive
4 position of the person from whom the information was obtained." Release of the redacted information
5 in the present case will not impair the FDA as it compels industry disclosure of necessary information
6 pursuant to its regulatory and statutory power. Furthermore, public revelation will not cause competitive
7 injury to the producers because the information simply reflects prevailing industry standards. Moreover,
8 Cal-Maine Foods, Feather Crest Farms, and Mahard Egg Farm waived confidentiality to the redacted
9 information by voluntarily supplying it to a third-party to verify compliance with the United Egg
10 Producers Certified ("UEP Certified") program.

11 3. ALDF is entitled to records without inappropriate redactions and the Court should grant
12 injunctive and declaratory relief accordingly.

13 PARTIES

14 4. ALDF, Plaintiff, is a national non-profit organization incorporated in California and
15 headquartered in Sonoma County. ALDF regularly seeks and utilizes public records to support its
16 mission of protecting the interests of animals through the legal system. As part of these efforts, ALDF
17 requested records from the FDA relating to egg safety and production in Texas in a December 15, 2011,
18 FOIA request.

19 5. The FDA, Defendant, is a federal agency within the United States Department of Health
20 and Human Services. The FDA qualifies as an agency under 5 U.S.C. § 552(f) and must comply with
21 FOIA requests. The FDA is headquartered in Silver Spring, Maryland. It maintains two offices in
22 Alameda County, California, for the PA Region and San Francisco District.

23 JURISDICTION

24 6. This Court has subject-matter jurisdiction over the action because it arises under a
25 federal statute and a United States agency is the defendant. 5 U.S.C. § 552(a)(4)(B); 28 U.S.C. §§ 1331
26 and 1346.

7. This Court has personal jurisdiction over the parties because ALDF, the complainant, is headquartered in Sonoma County in the Northern District of California. 5 U.S.C. § 552(a)(4)(B).

8. Venue is proper in the Northern District of California because ALDF, the plaintiff, is headquartered in Sonoma County, California. 5 U.S.C. § 552(a)(4)(B); 28 U.S.C. § 1391(e).

INTRADISTRICT ASSIGNMENT

9. Assignment to the San Francisco Division is appropriate because ALDF made the FOIA request and received FDA records at ALDF headquarters in Sonoma County, California. Therefore, a substantial part of the events giving rise to this action occurred in Sonoma County. Civil. L.R. 3-2(c) & (d).

LEGAL FRAMEWORK

Freedom of Information Act, 5 U.S.C. § 552

10. The Freedom of Information Act promotes open government by providing every person with a right to request and receive federal agency records. 5 U.S.C. § 552(a)(3)(A) and (f).

11. Agencies may promulgate rules stating the time, place, fees, and procedures to be followed in making FOIA requests. 5 U.S.C. § 552(a)(3)(A). FOIA procedures for the Food and Drug Administration are codified at 21 C.F.R. §§ 20.1, *et seq.* Coextensive FOIA procedures for the Department of Health and Human Services – of which the FDA is a subdivision – are codified at 45 C.F.R. §§ 5.1, *et seq.*

12. Despite its design to encourage open government, FOIA contains limited exemptions allowing some information to be withheld from the public. 5 U.S.C. § 552(b); *Lahr v. NTSB*, 569 F.3d 964, 973 (9th Cir. 2009). However, these exemptions are “specifically made exclusive . . . and must be narrowly construed.” *Dep’t of Air Force v. Rose*, 425 U.S. 352, 360-61 (1976). Additionally, “the burden is on the agency [invoking an exemption] to sustain its action.” 5 U.S.C. § 552(a)(4)(B).

13. An agency must comply with a FOIA request within 20 working days or immediately inform the requestor why an adverse determination was made and the right to appeal. 5 U.S.C. § 552(a)(6)(A)(i). A requester may appeal the FDA’s invocation of an exemption by sending a letter

1 within thirty days after receiving the redacted records. 5 U.S.C. § 552(a)(6)(A)(ii); 21 C.F.R. §
 2 20.41(b)(4); 45 C.F.R. § 5.34(a). The agency must make a determination within twenty working days
 3 whether the exemption applies and, if so, inform the requestor of provisions for judicial review. 5 U.S.C.
 4 §552(a)(6)(A)(ii).

5 14. An agency's failure to comply with any timing requirements is deemed constructive
 6 denial and satisfies the requestor's requirement of administrative exhaustion. 5 U.S.C. § 552(a)(6)(C)(i).

7 15. A FOIA requestor that has exhausted her administrative remedies may petition the court
 8 for injunctive and declaratory relief from the agency's continued withholding of public records. 5 U.S.C.
 9 § 552(a)(4)(B); *see, e.g., Oregon Natural Desert Ass'n v. Locke*, 572 F.3d 610, 612-14 (9th Cir. 2009).

10 **Exemption 4: Confidential Commercial Communications, 5 U.S.C. § 552(b)(4)**

11 16. Exemption 4 allows agencies to withhold "trade secrets and commercial or financial
 12 information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The Ninth
 13 Circuit construes Exemption Four as "prevent[ing] disclosure of (1) trade secrets and commercial or
 14 financial information, (2) obtained from a person or by the government, (3) that are privileged or
 15 confidential." *Pacific Architects & Engineers, Inc. v. United States Dep't of State*, 906 F.2d 1345, 1347
 16 (9th Cir. 1990).

17 17. The terms "commercial or financial" retain their ordinary meanings. *Watkins v. United*
 18 *States Bureau of Customs*, 643 F.3d 1189, 1194 (9th Cir. 2011).

19 18. Information is "privileged or confidential" if public release is likely to (1) "impair the
 20 government's ability to obtain necessary information in the future" or (2) "cause potential harm to the
 21 competitive position of the person from whom the information was obtained." *Pacific Architects*, 906
 22 F.2d at 1347.

23 19. Public disclosure does not impair an agency's ability to obtain necessary information in
 24 the future if the agency required production of that information from a regulated entity in the first place.
 25 *Franzee v. United States Forest Serv.*, 97 F.3d 367, 372 (9th Cir. 1996). Thus, the only way compelled
 26 information can qualify as confidential is when disclosure is nonetheless likely to cause substantial

1 competitive harm. *Id.*

2 20. Courts must carefully scrutinize claims of competitive harm under Exemption 4 and
3 place the burden on the agency to show specific and substantial competitive harm resulting from
4 disclosure. *In Def. of Animals v. NIH*, 527 F. Supp. 2d 23, 32 (D.D.C. 2007). The prevalence of
5 standardization within an industry may be dispositive of the question of competitive harm. *GC Mico*
6 *Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994). The burden remains on the
7 agency resisting disclosure to prove the economic conditions will lead to substantial competitive harm.
8 *Id.*

9 21. Confidentiality or privilege is waived altogether when information is disclosed to a third
10 party with the potential for broader dissemination. *Watkins*, 643 F.3d at 1197.

11 **Egg Safety Rule, 21 C.F.R. §§ 118.1, *et seq.***

12 22. The Food and Drug Administration issued the Egg Safety Rule in 2009 to regulate
13 salmonella contamination at egg production plants. Prevention of Salmonella Enteritidis in Shell Eggs
14 During Production, Storage, and Transportation, 74 Fed. Reg. 33,030 (July 9, 2009) (codified at 21
15 C.F.R. pt. 118, *et seq.*). This rule requires that “persons engaged in production of shell eggs must permit
16 authorized representatives of FDA to make . . . an inspection of the egg production establishment in
17 which shell eggs are being produced.” 21 C.F.R. § 118.12(b). Inspectors are authorized to inspect the
18 environment and equipment as well as examine and copy any records “as may be necessary in the
19 judgment of [the inspector].” *Id.*

20 23. The FDA’s authority to promulgate the Egg Safety Rule relies on two statutes: the
21 Public Health Service Act, 42 U.S.C. §§ 241, *et seq.*, and the Food, Drugs, and Cosmetics Act, 21 U.S.C.
22 §§ 321, *et seq.* Prevention of Salmonella Enteritidis in Shell Eggs, 74 Fed. Reg. at 33,049-50.

23 24. The PHSA authorizes [the FDA] “to develop . . . a plan . . . [to] control epidemics of any
24 disease [] and to meet other health emergencies or problems.” 42 U.S.C. § 243(c)(1). Additionally, the
25 PHSA authorizes the promulgation of regulations that “are necessary to prevent the . . . spread of
26 communicable diseases.” 42 U.S.C. § 264(a). Those regulations “may provide for such inspection . . . as

1 [] may be necessary.” *Id.*

2 25. The FDCA provides further statutory support for the Egg Safety Rule by generally
3 prohibiting the entry or movement of adulterated food in interstate commerce. 21 U.S.C. § 331. The
4 FDA may promulgate regulations, inspect records, and conduct inspections to satisfy this purpose. 21
5 U.S.C. §§ 371(a), 372, 373, & 374. A regulated entity’s refusal to permit access to records or inspection
6 under the FDCA is prohibited. 21 U.S.C. § 331(e) & (f).

7 FACTS

8 **ALDF’s FOIA Request to the FDA**

9 26. ALDF requested information from the FDA on December 15, 2011 seeking information
10 relating to egg safety and egg production in Texas. The FDA designated ALDF’s FOIA request FOI
11 #F2011-9390.

12 27. The FDA sent responsive records to ALDF on March 2, 2012. ALDF received this
13 response on March 7, 2012. A copy of the FDA’s cover letter with a list of enclosed documents is
14 attached as Exhibit A.

15 28. The FDA’s response included twelve “Establishment Inspection Report[s]” for the same
16 number of Texas egg production plants. The FDA conducted these inspections pursuant to its authority
17 under the Egg Safety Rule. A representative Establishment Inspection Report is attached as Exhibit B.

18 29. The FDA redacted information in fields relating to: total hen population, the number of
19 hen houses, the number of floors per house, the number of cage rows per house, the number of cage
20 tiers per house, and the number of birds per cage (hereinafter referred to generically as “hen population
21 and living conditions”). (Ex. B, at pp. 2, 5, 6, 9, 10, 11, 12, 19, 21, 22, 26.)

22 30. The FDA instructed ALDF that it could appeal this determination by sending a letter
23 requesting reconsideration to the Director of the News Division within thirty days. (Ex. A.) ALDF sent
24 such a letter to the FDA on March 30, 2012 requesting reconsideration of the redactions on the basis
25 that information relating to hen population and living conditions does not qualify as privileged or
26 confidential commercial information under Exemption 4.

1 31. Specifically, ALDF noted that the information was not voluntarily obtained by the FDA
 2 from the egg producers. ALDF then argued that the information was not privileged or confidential
 3 because public disclosure would not cause competitive harm to the egg producers because the redacted
 4 information simply reveals information that is standardized throughout the industry and too general to
 5 cause competitive harm.

6 32. The FDA acknowledged ALDF's appeal letter on April 7, 2012. The FDA has not
 7 rendered a ruling or requested an extension of the applicable deadline despite the lapse of over four
 8 months. The FDA therefore waived any administrative exhaustion requirements.

9 **Information about Hen Population and Living Conditions**

10 33. Egg producers throughout the industry follow similar hen population and living
 11 condition standards. These standards are largely set and reflected by guidelines published by the United
 12 Egg Producers ("UEP"). The UEP is a private trade cooperative whose members produce 97% of all
 13 eggs sold in the United States.

14 34. Approximately 95% of all commercial egg producers in the United States are large
 15 industrial operations with over 75,000 hens. Approximately the same number utilizes a battery cage
 16 production system where egg-laying hens are confined to stacks and rows of small cages lining the
 17 inside of large industrial barns.

18 35. The UEP's Animal Husbandry Guidelines ("Guidelines") include detailed instructions
 19 for taking care of egg-producing hens. Specifically, the Guidelines recommend that producers give 67
 20 square inches of cage space to each hen. The amount of space given to each hen is directly related to
 21 population density parameters like the number of floors per house, the number of cage rows per house,
 22 the number of cage tiers per house, and the number of birds per cage.

23 36. Disclosure of this information cannot cause competitive harm to egg producers. The egg
 24 industry coalesces around the same egg production model utilizing a battery cage system, tens of
 25 thousands of hens, and the same cage space allowances. Whatever slight variations exist between
 26 producers are insignificant such that disclosure will not cause substantial competitive harm.

1 37. The UEP also manages the "UEP Certified" animal welfare program. Participation in
 2 this program is voluntary. Eggs that are UEP Certified must comply with the UEP Guidelines. This
 3 includes the requirement that each hen receive 67 square inches of space. UEP Certified compliance is
 4 determined by audit. Upon information and belief, UEP Certified producers voluntarily submit
 5 information relating to hen population and living conditions as part of the audit process.

6 38. 80% of all eggs produced in the United States satisfy the UEP Certified guidelines.
 7 Participants in the UEP Certified program include three large Texas egg producers: Cal-Maine Foods,
 8 Feather Crest Farms, and Mahard Egg Farm. Ten of the twelve Establishment Inspection Reports the
 9 FDA produced to ALDF involved facilities owned and operated by these three producers.

10 39. The potential for competitive harm resulting from disclosure of information relating to
 11 hen population and living conditions is especially small with regards to the three UEP Certified
 12 producers. The UEP Certified producers are not only encouraged to follow the Guidelines relating to
 13 animal care and cage space but are affirmatively required to do so. Their provision of hen population
 14 and living condition information to a trade association that includes their competitors reveals a lack of
 15 intent for confidentiality, a lack of competitive harm from disclosure, and constitutes waiver of
 16 confidentiality.

17 40. In addition to the intra-industry dynamics described above, all producers are required by
 18 law to submit information to the FDA including hen population and living conditions. *See* 21 C.F.R. §
 19 118.12(b); 42 U.S.C. § 264(a); 21 U.S.C. § 331(e) & (f). FDA inspectors request this information from
 20 inspected facilities and include it in the Establishment Inspection Reports.

21 **CAUSE OF ACTION**

22 **Violation of the Freedom of Information Act**

23 41. The allegations in the preceding paragraphs are re-alleged and incorporated by reference
 24 as if fully set forth herein.

25 42. ALDF made a proper FOIA request for information relating to egg production in Texas.
 26 5 U.S.C. § 552(a)(3)(A). However, the FDA unlawfully withheld information from ALDF by redacting

1 information from Establishment Inspection Reports fields for: total hen population, the number of hen
2 houses, the number of floors per house, the number of cage rows per house, the number of cage tiers per
3 house, and the number of birds per cage.

4 43. The FDA redacted that information pursuant to Exemption 4 which requires that the
5 agency show the existence of confidential or privileged commercial information. 5 U.S.C. § 552(b)(4).
6 Information is confidential or privileged only if disclosure impairs the agency's ability to obtain
7 necessary information in the future or causes competitive harm to the person from whom the
8 information is obtained. *Pacific Architects*, 906 F.2d at 1347.

9 44. The FDA's ability to obtain necessary information in the future is not impaired by
10 disclosure of the challenged redactions because the egg producers were required to provide the
11 information in the first place. *See Franzee*, 97 F.3d at 372.

12 45. At the same time, disclosure of the redacted information will not cause competitive
13 harm to the egg producers. Information relating to hen population and living conditions is standardized
14 throughout the industry and disclosure therefore does not reveal anything that could cause substantial
15 competitive harm to a producer. *See GC Micro Corp.*, 33 F.3d at 1115. Any deviations from the
16 industry standards are insignificant and disclosure is likewise unable to cause substantial competitive
17 harm. Furthermore, Cal-Maine Foods, Feather Crest Farms, and Mahard Egg Farm waived
18 confidentiality by voluntarily supplying this information to a third-party to verify compliance with the
19 UEP Certified program. *See Watkins*, 643 F.3d at 1194.

20 46. ALDF exhausted the applicable administrative remedies by appealing the FDA's
21 unlawful redaction of requested information in a March 30, 2012 letter. 5 U.S.C. § 552(a)(6)(C)(i). The
22 FDA constructively denied ALDF's appeal by failing to issue a ruling or request an extension of time
23 within twenty working days. *Id.*; 5 U.S.C. § 552(a)(6)(A)(ii).

24 47. ALDF has suffered irreparable injury and has no relief at law other than injunctive and
25 declaratory relief.

26 48. Accordingly, ALDF has a right under FOIA to injunctive and declaratory relief against

1 the FDA for its unlawful withholding of the redacted information. 5 U.S.C. § 552(a)(4)(B).

2 **RELIEF REQUESTED**

3 WHEREFORE, Plaintiff seeks judgment as follows:

4 1. An order enjoining the FDA from withholding information in the Establishment
5 Inspection Reports fields for (i) total hen population, (ii) the number of hen houses, (iii) the number of
6 floors per house, (iv) the number of cage rows per house, (v) the number of cage tiers per house, and
7 (vi) the number of birds per cage;

8 2. An order requiring the FDA to produce the requested Establishment Inspection Reports
9 without redactions for (i) total hen population, (ii) the number of hen houses, (iii) the number of floors
10 per house, (iv) the number of cage rows per house, (v) the number of cage tiers per house, and (vi) the
11 number of birds per cage;

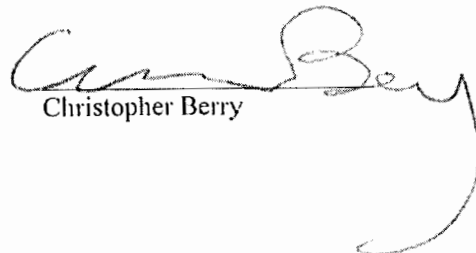
12 3. A declaration that it was unlawful for the FDA to fail to disclose (i) total hen population,
13 (ii) the number of hen houses, (iii) the number of floors per house, (iv) the number of cage rows per
14 house, (v) the number of cage tiers per house, and (vi) the number of birds per cage;

15 4. An award to Plaintiff of all costs and reasonable attorneys' fees as provided in 5 U.S.C.
16 § 552(a)(4)(E) or any other law; and

17 5. Grant other and further relief as the court may deem just and proper.

18
19 DATED: August, 16 2012

20
21 Respectfully submitted,

22 
23 Christopher Berry
24
25
26

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

March 2, 2012

Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

Chris Berry
Animal Legal Defense Fund
170 East Cotati Ave
Cotati, CA 94931

Reference: FOI #F2011-9390

Dear Mr. Berry:

In response to your December 15, 2011, request for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act:

X We are enclosing the requested record(s): see list of enclosures.

X Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously withheld information, you would have the right to appeal that decision. Any letter of denial will explain how to make this appeal. Please submit your appeal within 30 days to Director, News Division, 7700 Wisconsin Avenue, Suite 920, Bethesda, MD 20857 (by U.S. Post), or 7700 Wisconsin Avenue, Suite 920, Bethesda, MD 20814 (by private courier, such as UPS or FedEx). Please mark your envelope FDA FOIA.

The following charges may be included in a monthly invoice:

Reproduction \$ 37.90 Search \$N/A Review \$ N/A Other \$10.00 Certification + \$1.00
CD Total: \$48.90

The above total may not reflect final charges for this request. Please do not send payment unless you receive an invoice for the total monthly fee.

Sincerely yours,

A handwritten signature in cursive script that reads "Patrick J. Kaelin".

Patrick J. Kaelin
Information Disclosure Officer

Enclosure(s): As indicated

EXHIBIT A

List of Enclosures

- A. Cal-Maine Foods, Farwell, Texas
 - 1. Establishment Inspection Report regarding the inspection which was completed 3/11/2011;
 - 2. Form 483 which was issued to the firm on 3/11/2011; and
 - 3. Letter to the firm dated 4/25/2011.

- B. Cal-Maine Foods, Flatonia, Texas (FEI number 3004299311)
 - 1. Establishment Inspection Report regarding the inspection which was completed 7/15/2011; and
 - 2. Letter to the firm dated 9/22/2011.

- C. Cal-Maine Foods, Flatonia, Texas (FEI number 3004299378)
 - 1. Establishment Inspection Report regarding the inspection which was completed 7/21/2011; and
 - 2. 483 which was issued to the firm on 7/21/2011;
 - 3. Amended 483 which was issued to the firm on 9/20/2011;
 - 4. Letters from the firm which were received 7/23/2011;
 - 5. Letter to firm dated 8/1/2011; and
 - 6. Letter to the firm dated 9/22/2011.

- D. Cal-Maine Foods, Harwood, Texas (FEI number 3004284274)
 - 1. Establishment Inspection Report regarding the inspection which was completed 6/17/2011;
 - 2. 483 which was issued to the firm on 6/17/2011;
 - 3. Letter from the firm dated 6/30/2011; and

4. Letter to the firm dated 7/18/2011.

E. Cal-Maine Foods, Harwood, Texas (FEI number 3004298891)

1. Establishment Inspection Report regarding the inspection which was completed 7/21/2011;
2. 483 which was issued to the firm on 7/21/2011;
3. Letter from the firm (undated);
4. Letter to the firm dated 8/4/2011;
5. Sample 531679 which was collected on 7/20/2011; and
6. Letter to the firm dated 9/16/2011.

F. Cal-Maine Foods, Waelder, Texas (FEI number 3004298859)

1. Establishment Inspection Report regarding the inspection which was completed 6/21/2011;
2. 483 which was issued to the firm on 6/21/2011; and
3. Letter to the firm dated 7/18/2011.

G. Cal-Maine Foods, Waelder, Texas (FEI number 3004327922)

1. Establishment Inspection Report regarding the inspection which was completed 7/26/2011;
2. Letter from the firm (undated);
3. Letter to the firm dated 8/8/2011; and
4. Letter to the firm dated 9/22/2011.

H. Ditta Meat Company, Pasadena, Texas

1. Establishment Inspection Report regarding the inspection which was completed 4/28/2011;
 2. Form E-14 issued to the firm on 4/28/2011; and
 3. Letter to the firm dated 6/28/2011.
- I. Feather Crest Farms, Bryan, Texas
1. Establishment Inspection Report regarding the inspection which was completed 7/25/2011;
 2. Form 483 issued to the firm on 7/25/2011 and;
 3. Letter to the firm dated 9/22/2011.
- J. Feather Crest Farms, Center, Texas
1. Establishment Inspection Report regarding the inspection which was completed 9/9/2011;
 2. Form 483 issued to the firm on 9/9/2011 and;
 3. Letter to the firm dated 10/5/2011.
- K. First Produce, San Antonio, Texas
1. Establishment Inspection Report regarding the inspection which was completed 3/9/2011; and
 2. Letter to the firm dated 10/24/2011.
- L. Kieke Egg Farm, Burton, Texas
1. Establishment Inspection Report regarding the inspection which was completed 9/12/2011; and
 2. Letter to the firm dated 10/5/2011.

M. Mahard Egg Farm, Chillicothe, Texas

1. Establishment Inspection Report regarding the inspection which was completed 7/27/2011;
2. Form 483 issued to the firm on 7/27/2011 and;
3. Letter to the firm dated 9/21/2011.

N. Ruby's Quail Farm, Gordonville, Texas

1. Establishment Inspection Report with FDA Acidified Food Inspection Report regarding the inspection which was completed 9/20/2011;
2. Form 483 issued to the firm on 9/20/2011;
3. Sample 641163 which was collected on 9/20/2011;
4. Letter from the firm dated 10/1/2011;
5. Letter to the firm dated 10/17/2011; and
6. Letter to the firm dated 3/1/2012

O. Southwest Traders, Dallas, Texas

1. Form 483 issued to the firm on 8/4/2011;
2. Letter from the firm which was received 8/22/2011;
3. Letter to the firm dated 8/25/2011;
4. Warning Letter issued to the firm dated 10/25/2011; and
5. Letter from the firm dated 11/16/2011.

Establishment Inspection Report
 Cal-Maine Foods, Inc.
 Farwell, TX 79325-3586

FEI: 3007309456
 EI Start: 03/08/2011
 EI End: 03/11/2011

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Establishment Inspection Report

Cal-Maine Foods, Inc.
Farwell, TX 79325-3586

FEI: 3007309456

EI Start: 03/08/2011

EI End: 03/11/2011

SUMMARY

This comprehensive inspection of a Shell Egg Producer was conducted pursuant to high priority **FACTS assignment # 1257067**, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFPG Assignment # 11-04, ORA Concurrence # 2011012601, dated February 3, 2011 Amended February 8, 2011, and the DAL-DO FY 11 work plan. The inspection followed the guidance given in the assignment, and requirements of the "Egg Rule" written in 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. The inspection was pre-announced to the firm's General Manager, Mr. Michael A. Gibson on 03/03/2011.

The producer operates (b) (4) egg houses at the same physical address. Environmental samples were collected from four hen houses and documented in Collection Reports for Investigative Samples #INV648672, INV648673, INV604287 and INV604288. The samples were collected from the (b) (4) poultry houses to assess conditions and obtain baseline information about the state of the industry. Each house sampled was a (b) (4) house. Each house contained (b) (4) floors. Each floor contained rows with tiers that each contained a scraper blade and a manure belt. The samples were analyzed for Salmonella Enteritidis (SE). All samples were negative for Salmonella Enteritidis (SE).

The main objectives of the inspection were to:

- Assess compliance with 21 CFR 118 including evaluation of the firm's SE prevention plan, egg laying operation, environmental monitoring and documentation.
- Conduct environmental sampling and inspection of egg laying facilities to determine if the firm is practicing adequate measures to prevent SE contamination of eggs and egg production areas.

Additionally, the inspection was to determine individual responsibility for the firm's SE prevention plan, who owns the layer hens, and who packages the eggs. Documents reviewed during the inspection included the firm's written SE Prevention Plan and Bio-Security Plan, pullet receiving records, pest control records, and refrigeration records.

This was the first FDA inspection of Cal-Maine Foods, Inc. The inspection found that the firm has a written SE prevention plan to cover the firm's production facility.

Objectionable conditions were observed during the current inspection and a 1-item FDA 483 – Inspectional Observations was issued which included the following:

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1. Not taking adequate steps to assure that there is no introduction or transfer of SE into or among poultry houses. Wheelbarrows are a potential source of SE contamination into and between Houses (b) (4)

The firm instructed employees not to bring the mortality wheelbarrows into the layer houses. The firm will respond to FDA in writing regarding this observation within 14 business days.

The last recall conducted by the firm was on 08/20/10. The firm purchased the eggs from (b) (4) (b) (4) for direct shipment and did not receive any of the purchased eggs on-site. Customer notification of the recalled product was conducted by the firm's corporate office in Jackson, MS. All of the eggs were accounted for.

There were no refusals encountered during the inspection. All firm registrations are current. Mr. Michael A. Gibson, General Manager promised to correct all FDA 483, Inspectional Observations.

A response in writing to the FDA 483 from Ruben Acevedo, Compliance Manager was received by fax on April, 1, 2011. See Additional Information section of this report for further information regarding the response letter.

ADMINISTRATIVE DATA

Inspected firm: Cal-Maine Foods, Inc.
Location: 410 F.M. 3333
Farwell, TX 79325-3586
Telephone: 806-825-2245
FAX: 806-825-2250

Mailing address: 410 F.M. 3333
Farwell, TX 79325-3586

Contact persons: Mr. Michael A. Gibson, General Manager
Email: mgibson@cmfoods.com
Mr. Ruben Acevedo, Compliance Manager
Mr. Robert "Bob" Burger, Production Manager
Mr. James Davis Wilbourn, Processing Manager

Corporate headquarters: Cal-Maine Foods, Inc.
3320 Woodrow Wilson Avenue
Jackson, MS 39209
Telephone: 601-948-6813

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FAX: 601-949-7845

Contact persons: Mr. Fred Adams, Jr., C.E.O. and Chairman of the Board
Ryn L. McDonald, Ph.D., Director of Food Safety
Email: rmcDonald@cmfoods.com

Dates of inspection: 3/8/2011, 3/9/2011, 3/10/2011, 3/11/2011

Days in the facility: 4

Participants: Brandon K. Barbee, Investigator
Grant L. Davis, Investigator
Paul E. Frazier, Investigator

On 03/08/2011, at the initial meeting with Mr. Michael A. Gibson, General Manager, Cal-Maine Foods, Inc., Farwell, TX, We, Brandon K. Barbee, Paul E. Frazier and Grant L. Davis, Investigators displayed our credentials and issued a Form FDA 482, Notice of Inspection (**Attachment 1**) to Mr. Gibson who identified himself as the most responsible individual at the firm. An FDA 483, Inspectional Observations (**Attachment 3**) and an FDA 484, Receipts for Samples (**Attachment 4**) for environmental samples taken during the course of the inspection and were issued to Mr. Michael A. Gibson at the close of the inspection on 03/11/2011.

Mr. Michael A. Gibson, General Manager of Cal-Maine Foods, Inc. provided brief information to us and assisted us throughout the inspection. Mr. Ruben Acevedo, Compliance Manager, and Mr. Bob Burger, Production Manager also accompanied us during portions of the inspection and provided us with the information exhibited in this report.

This was a team inspection conducted by Brandon K. Barbee serving as Lead Investigator with Investigator Grant L. Davis and Investigator Paul E. Frazier. All Investigators were in attendance throughout the inspection representing the FDA.

During the Close-Out Meeting Mr. Michael A. Gibson, General Manager and Mr. Robert (Bob) Burger, Production Manager were in attendance representing the Firm:

Cal-Maine Foods, Inc. is also regulated by USDA. Mr. Jim French is the USDA Resident Grader and is located on site at the firm.

All sections of this report were written by Investigator Brandon K. Barbee unless otherwise stated.

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HISTORY

Written by Paul E. Frazier

Cal-Maine Foods, Inc. operates as a manufacture, packager, and distributor of shelled eggs. The firm Cal-Maine Foods, Inc. is 1 of 7 shelled egg facilities in Texas. Constructions of the facility begin in September 2007. In 2009, Cal-Maine Foods, Inc. suffered a fire which ended with the loss of hen laying complexes, pullet house, and manure storage building. Rebuilding of the facility after fire was finished in September 2010. The facility is located on approximately (b) (4) acres which include (b) (4) (b) (4) hen laying complexes, pullet houses, manure storage buildings, cooler, and processing room. The firm also has a manufacturing plant for feed on site.

Cal-Maine Foods, Inc. distributes eggs in the size of medium, large, X-Large, and Jumbo. These products are distributes under their company label and various other private labels.

Annual sales for 2010 were approximately \$(b) (4)

The corporate office is located at 3320 Woodrow Wilson Drive, Jackson, MS 39209.

The firm operates (b) (4) The firm's general office hours are Monday-Friday 8:00AM – 4:00PM.

The firm has a national website at: <http://www.calmainefoods.com>

Post inspection and FMD-145 correspondence should be addressed to:

Mr. Michael A. Gibson, General Manager
Cal-Maine Foods, Inc.
410 F.M. 3333
Farwell, TX 79325-3586

INTERSTATE COMMERCE

Mr. Michael Gibson, General Manager stated that approximately (b) (4)% of Cal-Maine Foods, Inc. egg production is distributed outside the state of Texas. He stated that the firm owns the hens and the eggs they lay. The firm is a (b) (4)% wholesale.

The firm largest three customers are as follows:

- (b) (4)
- (b) (4)
- (b) (4)

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The firm does not give bill of lading to their customers only Invoices. Mr. Gibson provided copies of the following documents showing interstate distribution of eggs:

- Cal-Maine Foods, Inc. Document number 24004745, dated 02/18/2011 showing sales including cases shipped to (b) (4) (see Exhibit 1)
- Cal-Maine Foods, Inc. Document number 24004808, dated 02/26/2011 showing sales including cases shipped to (b) (4) (see Exhibit 2)
- Cal-Maine Foods, Inc. Document number 24004746, dated 02/18/2011 showing sales including cases shipped to (b) (4) (see Exhibit 3)

The following copies of documents provided by the firm, showing interstate shipment of pullets from (b) (4)

- National Poultry Improvement Plan (NPIP) Report # Y073189, Report of Sales of Hatching Eggs, Chicks, and Poults, showing that (b) (4) variety poults (pullets) from the load were sold to Cal-Maine Farms, Farwell, TX on 8-31-2010. (see Exhibit 11 top of page 1).
- National Poultry Improvement Plan (NPIP) Report # X089972, Report of Sales of Hatching Eggs, Chicks, and Poults, showing that (b) (4) variety poults (pullets) from the load were sold to Cal-Maine Farms, Farwell, TX on 7-06-2010. (see Exhibit 11 bottom of page 1).
- National Poultry Improvement Plan (NPIP) Report # Y073305, Report of Sales of Hatching Eggs, Chicks, and Poults, showing that (b) (4) variety poults (pullets) from the load were sold to Cal-Maine Farms, Farwell, TX on 1-25-2011. (see Exhibit 11 top of page 2).
- National Poultry Improvement Plan (NPIP) Report # Y074078, Report of Sales of Hatching Eggs, Chicks, and Poults, showing that (b) (4) variety poults (pullets) from the load were sold to Cal-Maine Farms, Farwell, TX on 11-08-2010. (see Exhibit 11 bottom of page 2).

JURISDICTION

The firm is a Shell Egg Producer with greater than (b) (4) laying hens that produce shell eggs for the table market and is subject to requirements in 21 CFR 118: Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage and Transportation. The firm is registered with the FDA.

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INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED*Written by Paul E. Frazier*

Mr. Michael A. Gibson, General Manager, Cal-Maine Foods, Inc., Farwell, TX – Mr. Gibson informed me that he has been employed by Cal-Maine Foods, Inc. for 3 ½ years. Mr. Gibson informed me that he is the most responsible individual at the firm. He informed that he is responsible for the overall operations and management of the farm. He oversees the compliance manager, production manager, processing manager, accounting manager, feed mill manager, and sales/distribution manager and the different areas of the farm. ^{(b) (4)} employees report to Mr. Gibson. Mr. Gibson informed me that he has the ability to hire and fire. Mr. Gibson informed me that he has the ability to spend up to ^{(b) (4)} dollars for repairs or products needed for the facility. Mr. Gibson informed me that he reports to the Vice President of Operations, Steve Storm. During the inspection Mr. Gibson accepted the FDA 482, Notice of Inspection as the most responsible individual at the firm. He also accepted the FDA 483, Inspectional Observation form. Mr. Michael A. Gibson, General Manager promised to correct all FDA 483, Inspectional Observations.

Mr. Gibson accompanied us around the facility and during the sampling. He also provided information that was relevant to the inspection. To see an organizational chart of all the individual who report to Mr. Gibson (see Exhibit 4).

Mr. Ruben Acevedo, Compliance Manager, Cal-Maine Foods, Inc., Farwell, TX – Mr. Acevedo informed me that he has been employed by Cal-Maine foods for 2 ½ years. Mr. Acevedo informed me that he oversees the HACCP program, Food Security Program, Animal Welfare & United Egg Production (UEP) programs. Mr. Acevedo informed me that he conducts facility inspections and safety training in all departments. He informed me that he oversees the environmental sampling that is done and conducts training with the supervisors on how to conduct the sampling. In general Mr. Acevedo handles all aspects of compliance for the firm. Mr. Acevedo accompanied us around the facility and during the sampling. He also provides information that was relevant to the inspection such as environmental sampling records and employee training records. Mr. Acevedo reports to Mr. Michael Gibson, General Manager.

Mr. Robert "Bob" Burger- Production Manager, Cal-Maine Foods, Inc., Farwell, TX – Mr. Burger has been employed with Cal-Maine Foods for 10 years. He has been at this facility since December 2007. Mr. Burger informed me that he oversees supervisors and employees in the pullet and hen laying complexes. Mr. Burger is responsible for ensuring all animal husbandry guideline and animal welfare standards are followed. He also informed me that he oversees the utility farm staff. The pullets' supervisors, layers supervisor, and the flock service supervisor all report to Mr. Burger. During the inspection Mr. Burger accompanied us around the facility and during the sampling. He also provides information that was relevant to the inspection. Mr. Burger reports to Mr. Michael Gibson, General Manager.

Mr. James Davis Wilbourn, Processing Manager, Cal-Maine Foods, Inc., Farwell, TX – Mr. Wilbourn informed me he has been employed by Cal-Mine Foods for 10 years and has been the

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Processing Manager at this facility for 2 years. Mr. Wilbourn informed me that he oversees all plant operations and staff. Mr. Wilbourn informed me that he is responsible for the processing department and shipping and receiving departments. Mr. Wilbourn informed me that he is responsible for overseeing that a quality of finished products and ensuring that all HACCP and food safety standards are being met. Mr. Wilbourn informed me that he arranges schedules for all staff members. During the inspection Mr. Wilbourn provided relevant information about the shipping department and the employees of the department. Mr. Wilbourn reports to Mr. Michael Gibson, General Manager.

The most responsible individual in the Cal-Maine Foods Corporations is Mr. Fred Adams, Jr., CEO and Chairman of the Board. Mr. Adams office is located at the corporate office in Jackson, MS. To view an organizational chart of the entire company (see **Exhibit 5**).

FIRM'S TRAINING PROGRAM

Mr. Ruben Acevedo, Compliance Manager, oversees the training program for the firm. The firm trains all employees on critical procedures annually. He stated that new employees are trained in all critical procedures before starting work and then trained on-the-job in specific areas. I reviewed training records for SE Training, Swabbing Training, Rodent trapping and baiting training, Disinfecting Layers and treating with pesticides records, foot bath training. The training records are updated by Mr. Ruben Acevedo, when a training is completed.

MANUFACTURING/DESIGN OPERATIONS

At the start of our inspection, Mr. Michael A. Gibson, General Manager reported that the firm had no current SE positive houses. He stated that the firm has been conducting "exit bird testing" for SE since the facility has opened. He explained that this involves environmental sampling and testing at the time of house depopulation and if a molt occurs. In addition, the firm will conduct environmental testing at the 15-16 week age of the flock, and the 40-45 week flock age specified in the egg rule. Mr. Gibson stated that although it was not part of the SE Prevention Plan, that all birds are vaccinated (b) (4) times [redacted] nasal sprays of live SE: [redacted] shot of dead SE).

SE Prevention / General

The firm provided a copy of their Cal-Maine Foods, Inc Salmonella Enteritidis Prevention Plan created June, 07, 2010; revised on July 7, 2010. The plan was written by Ryn L. McDonald, Ph.D., Director of Food Safety and approved by the Executive Committee. The on-site plan administrator is Michael A. Gibson, General Manager. The plan was signed by Ryn Laster McDonald, Ph.D. on 10/04/2010 and Mr. Michael A. Gibson, General Manager on 10/06/2010. (see **Exhibit 6**).

The firm's written SE Prevention Plan was in compliance with the five parts of the SE Rule. The plan consisted of the following:

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1. SE-Monitoring of Pullets
2. Biosecurity
3. Rodent/Pest Control
4. Poultry House Cleaning and Disinfect
5. Refrigeration

Hen House Design and Operation

Constructions of the facility begin in September 2007. In 2009, Cal-Maine Foods, Inc. suffered a fire which ended with the loss of hen laying complexes, pullet house, and manure storage building. Rebuilding of the facility after fire was finished in September 2010. The facility is located on approximately (b) (4) acres which includes (b) (4) hen laying complexes, pullet houses, manure storage buildings, cooler, and processing room. The firm also has a manufacturing plant for feed on site.

The firm provided a copy of a site map showing plant and complex identification and locations (see Exhibit 7 page 32 A and 32B). According to Mr. Michael A. Gibson, General Manager, Cal-Maine Foods, Inc. operates hen houses and pullet houses. Exhibit 8, Photos 1-5 the general setting and conditions. The firm's hen houses (b) (4) are dedicated to age specific flocks. He explained that the firm consists of a USDA monitored shell egg plant connected to hen houses by a system of common egg conveyors. He provided the hen house identification, association with egg plant, and shell egg producers registration numbers as follows:

USDA Plant ID # P2-007, Houses (b) (4)

All hen houses are wood frame structures with concrete and/or partially wood foundations, metal roofs, and metal siding. The firm has (b) (4) houses. The number of hens, age of hens, and temperature of each house can be seen at Exhibit 9. Each house consists of (b) (4) rows and (b) (4) tiers high. There are (b) (4) birds per cage. The manure is air dried and the manure belts are ran (b) (4) a week. The firm has (b) (4) manure collection houses. The manure is collected on a as need basis and is sold to be used as fertilizer. The firm has a feed lot located onsite to supply feed for the facility. A feed ingredients formulation sheet can be seen at Exhibit 10. The firm also has a refrigerated building to store the mortality birds.

Pullets

Cal-Maine Foods, Inc. has tested all breeder flocks for SE for a number of years prior to the implementation of the FDA Egg Safety Rule that became into effect July, 09, 2010. Because it was not required to be checked with on the NPIP certificate accompanying chicks, this item was not checked on the certificate. Since July 9, 2010, the firm's pullets test results are kept on file at corporation's hatcheries. When firm purchases the baby chicks from the hatcheries the paper work and all certificates indicate that breeder flocks are tested for SE and are S. Enteritis clean. The pullets are vaccinated for SE (b) (4) times. The pullets are also tested for (b) (4) The

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pullets documentation indicated that the pullets were (b) (4) clean. The firm provided pullets documentation during the inspection. An example of the NPIP Certificates for pullets documentation can be seen at **Exhibit 11**. Additionally, the firm will take environmental samples of manure with drag swabs samples for the pullets and send the swabs to (b) (4) (b) (4). The analytical results can be seen at **Exhibit 12**.

Biosecurity Program

The firm has a written Biosecurity program. The Biosecurity Plan covers: visitors, wild birds, vehicles, loose chickens, wasted feed, dead birds removal. A copy of the firm's Biosecurity Program can be seen on **Exhibit 7 page 4, 5 and 6** of the firm's SE Prevention Plan. The plan requires all visitors to read and sign the Biosecurity Program.

On 3/8/2011, I Brandon K. Barbee, Paul E. Frazier, Grant L. Davis, Investigators were provided with Cal-Maine Foods, Inc. Production House Visitor Guidelines for signatures. It was explained to Mr. Michael A. Gibson, Plant Manager that FDA investigators are not allowed to sign any of the firm's documentation. We did read through the Biosecurity Program, but did not sign any documentation. The Biosecurity Plan does not allow photographs to be taken onsite. Mr. Michael A. Gibson, General Manager, did not refuse photography. The Cal-Maine Foods, Inc. Production Visitors Guidelines can be seen at **Exhibit 7 page 8**. All contract service providers are required to sign the Production Visitors Guidelines. A list of the firm's vendors can be seen at **Exhibit 7 page 6 of the SE Prevention Plan**. When entering the farm a sign is posted that the farm is a Biosecure Farm. The firm posted the two signs in English and Spanish in the front office and beside the main entry point at the entrance to the production houses. The Biosecure Farm signs can be seen at (see **Exhibit 7 page 10 of the firm's SE Plan**).

Environmental Testing Program

The firm has a written SE Swabbing Schematic to identify how all rows will be sampled in each house. The firm will environmentally test pullet houses at 14-16 weeks of age. The layer houses will be tested 40-45 weeks of age. The firm will also environmentally test from the point when the laying hens are at 100% egg production. The firm will also conduct environmentally sampling when a (b) (4) (b) (4). The firm will use drag swabs to swab each tier of each row and each egg belt. The firm's Environmental Sampling log with results can be seen at **Exhibit 12 pg. 1-14**. The firm's SOP for Manure Belt Poultry House sampling can be seen in the firm's SE Plan on **Exhibit 13**.

The firm has a written procedure for segregating eggs following an Environmental Positive for SE. The firm will run the clean houses first and pull the clean eggs out of the clean hen houses. Then the SE Positive egg belts will be run last. The full procedure for segregating Eggs can be seen at **Exhibit 7 page 16**.

The firm also has a written procedure for the processing side. The processing side is where the eggs are packaged and refrigeration of the eggs occurs. The processing side is under 24 hour USDA

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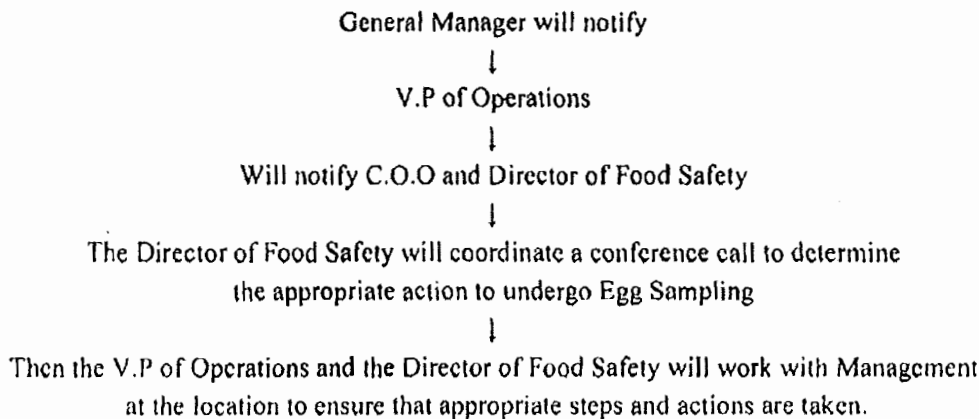
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surveillance and USDA personnel are always present during operational hours of the facility. All eggs are package and labeled SE Positive. Then once the eggs are properly labeled SE Positive all eggs are place in the refrigeration cooler in a designated area.

If the firm does have an environmental positive sample or test the General Manager of the firm will notify the Executive Committee. The firm has a written procedure to notify the chain of command. The chain of command will work with management at the location to ensure that appropriate steps and actions are taken.

The organizational structure is listed below:

**Egg Testing for SE**

In the event of a positive sample environmental SE Test the firm will collect (b) (4) egg samples (i.e., (b) (4) eggs plus (b) (4) eggs extra due to potential breakage during shipping to the laboratory) from each tier in the effected house. The eggs will be a representative sample from that day's production. A complete plan for Egg Testing for SE can be seen at Exhibit 7 pg. 57.

Personnel Movement

The firm does not have any SE Positive houses on site. The firm is currently operating under their SE Negative Environment Procedures. The firm has one foot bath located at the employee entrance which is stated in the SE Plan. When the employees walk through the footbath the employee will be allowed per the SE Plan to travel from house to house throughout the day to complete their work assignments. All tools and equipment needed to perform assignments per the SE Plan are permitted to be used in all houses. This includes but is not limited to cleaning tools (brooms for example) as well as maintenance tools and machinery. However, if the employees exit the houses the employees, the must re-enter back through the house that contains the boot dipping stations. There is one boot dipping station dedicated for the (b) (4) layer houses and one boot dipping station for the pullet houses.

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The boot dipping stations will be cleaned and service (b) (4) or if they become heavy soiled. The Boot Dipping Station Procedures can be seen at Exhibit 7 pg. 31

In the event an environmental positive is found, that house will be segregated and completely isolated from all other flocks. All doors leading into the house will be posted quarantined from unauthorized employees. Minimal employees will be assigned to perform work duties in that house on an as need basis. Required employees will enter and exit from that house only. All equipment and tools need for employees to perform work assignments will be assigned to that house and shall not leave.

The firm pulls dead birds from the house on a daily basis using dedicated wheel burrows for each house. The wheel burrows are pushed up and down each row gathering dead chickens. The firm uses dedicated wheel burrows for each house some of the wheel burrows were not numbered and two wheel burrows were stored outside of house one. See Objectable Conditions and Management's Response section Observation #1 of this report for further information.

The firm considers that all (b) (4) houses as one flock. If the house does have a positive environmental sample the firm will delegate that house as a SE Positive house, that house will be put on Daily Operating Procedures for SE positive conditions. In the event an environmental positive is found, that house will be segregated and completely isolated from all other flocks. All doors leading into the house will be posted quarantined from unauthorized employees. Minimal employees will be assigned to perform work duties in that house on an as need basis. Required employees will enter and exit from that house only. All equipment and tools need for employees to perform work assignments will be assigned to that house and shall not leave.

Flock Management

Mr. Michael A. Gibson, General Manager stated that he operates the hen houses as all in / all out meaning that at the end of the flock production cycle (usually about (b) (4) weeks) the entire house is de-populated as a group, and when ready, the house is re-populated with SE Clean pullets consisting of one flock of approximately the same age. He stated that all pullets are purchased from corporate hatcheries and raised in the (b) (4) pullet houses located on-site.

Cleaning and Disinfection

Cal-Maine Foods, Inc. will clean and disinfect at depopulation. The firm is not required to clean and disinfect at depopulation. However, it is considered preventative care for the houses. This was decided by the Executive Committee. The firm has a written Cleaning & Disinfecting Procedure for SE Negative Houses. The cleaning and disinfection occurs before the arrival of a new flock. The C/D procedures consist of a dry cleaning and a wet cleaning procedure. The C&D Procedure can be seen at Exhibit 7 pg. 21.

The firm has a written more labor intensive Dry and Wet Cleaning Procedure for an SE Positive houses. A Cleaning and Disinfecting Inspection Form is completed. When the C&D is completed, upper management has to verify that the C&D procedures were performed correctly. The verification

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can be only completed by Mr. Michael Gibson, General Manager, Mr. Bob Burger, Production Supervisor, Mr. Dan Fouts, Ms. Trinity Snider, Ms. Kelly Lindley, and Mr. Ruben Acevedo, Compliance Manager. The procedure can be seen at **Exhibit 7 pg. 22-23**.

Refrigeration

The firm has a written procedure for refrigeration requirements. The written procedure can be seen at **Exhibit 7 pg. 56**. The firm's cooler is located onsite and the temperature measurements are taken (b) (4). The firm has set a refrigeration requirement between (b) (4) degrees Fahrenheit. The firm will notify maintenance personnel if temperature requirements fall out of range. However, if the cooler temperatures cannot be brought back into range within [redacted] hours, finished product will be moved to a refrigerated trailer. Refrigeration records were reviewed during the inspection; nothing objectionable was noted and all refrigeration temperature/records were in range. The firm uses a digital thermometer which is calibrated (b) (4).

MANUFACTURING CODES

Mr. Ruben Acevedo, Compliance Manager stated that eggs produced in hen houses are packaged and labeled with the USDA Plant ID; P-1084, Julian date and expiry date.

COMPLAINTS

The firm maintains a complaint log. The firm's complaints were reviewed during the inspection. When the firm receives a complaint Ms. Theresa Osborne, Customer and Distribution Manager will complete a Complaint Investigation Form. Then the Complaint Investigation Form will be reviewed by Mr. Michael A. Gibson, General Manager. The complaints that were reviewed during the inspection were in regards to the egg case boxes not being tape properly. The firm has not had any complaints regarding to illness.

RECALL PROCEDURES

The firm has a written recall procedure. The firm's recall procedure was reviewed during the inspection. The firm will complete two mock recalls a year.

The firm had to conduct a recall on 08/20/10. The firm purchased (b) (4) half cases of SM Loose Large Dozen Eggs were bought from (b) (4) which were delivered to (b) (4). This was a direct shipment from (b) (4) to the (b) (4) Facility. All products were accounted for. Customer notification of the recalled product was conducted by the firm's corporate office in Jackson MS. All eggs were accounted for.

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OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Present at the close-out meeting for the firm was Mr. Michael A. Gibson, General Manager and Mr. Robert "Bob" Burger, Production Manager. I, Brandon K. Barbee serving as Lead Investigator with Investigator Grant L. Davis and Investigator Paul E. Frazier were present representing the FDA during the close-out meeting.

During the closeout meeting with the firm, we informed them that the observations made were only our observations and would be further reviewed by the agency. We stated that the following legal actions could be taken if the product was determined by the FDA to be violations of the Food Drug and Cosmetic Act: warning letters, seizure, injunctions and prosecution.

Observations listed on form FDA 483**OBSERVATION 1**

You have not taken adequate steps to assure that there is no introduction or transfer of SE into or among poultry houses.

Specifically, your employees move mortality layers from the (b) (4) Poultry Houses #LC (b) (4) through LC- (b) (4) to the one mortality building using wheelbarrows. The employees move the wheelbarrows to and from the individual poultry houses and the one mortality building through the exterior doors on each poultry house, across a dirt road which runs adjacent to the poultry houses, down an ~5' embankment, across 1 of 2 metal grates (~10' long x 2' wide with 3/4" holes lying in the wet sand and water) in a drainage ditch, up an ~5' embankment, across an ~100' dirt parking lot to the mortality building. The poultry houses are located ~3-500' from the mortality building.

1. On the far sides of both of these two drainage ditch crossing points are (b) (4) elevated manure conveyors which transport dry manure from the poultry houses into the manure building. Manure was observed on the ground and in the water which had dropped from the above conveyors into the drainage ditch. The firm does not have an SOP for cleaning up the manure which drops from the manure conveyors into the drainage ditch.
2. Birds were observed on the ground underneath the manure conveyors in the drainage ditch. Bird tracks were observed in the wet sand next to the two metal grates which cross the drainage ditch. We observed on two occasions the front rubber tire of one wheelbarrow make contact with the dirt, the metal grate, the wet sand and the water.
3. Feathers, dry manure, wet manure and/or filth were observed in empty wheelbarrows being stored outside on a concrete patio next to the exterior doors of the (b) (4) poultry houses. Feathers, dry manure and/or filth were observed in empty wheelbarrows being stored inside the (b) (4) poultry houses.

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The wheelbarrows are a potential source of SE introduction into the (b) (4) poultry houses. Your firm does not have an SOP for the cleaning and sanitizing of wheelbarrows in your SE Plan.

Reference: 21 CFR 118.4(b)

Supporting Evidence and Relevance:

Grant L. Davis, Investigator was responsible for this observation and wrote this section of this report.

- Wheelbarrows are used to store and transport mortality layers from the (b) (4) Poultry Houses #LC- through LC- to the one mortality building.

See Exhibit #14 – Four (4) pictures of wheelbarrows used to store and transport mortality layers from the (b) (4) layer houses to the mortality shed; Picture files: Cal-Maine 030911 939.jpg, Cal-Maine 030911 1149.jpg, Cal-Maine 030911 1205-2.jpg and Cal-Maine 030911 1205.jpg (4 pages)

- The wheelbarrows containing mortality layers exit the layer houses through a double-door and cross a dirt road to the drainage ditch. After the wheelbarrows return from the mortality shed, the wheelbarrows are stored outside on the concrete patios. When needed inside the layer house, the employees bring the wheelbarrows into the layer house through the double-door on the patio.

See Exhibit #15 – Two (2) pictures of the dirt road and drainage ditch the wheelbarrows cross to travel from the (b) (4) layer houses to the mortality shed; Picture files: Cal-Maine 030911 1204-3.jpg and Cal-Maine 030911 1204-4.jpg

- On the far sides of both of these two drainage ditch crossing points are (b) (4) elevated manure conveyors which transport dry manure from the poultry houses into the manure building. Manure was observed on the ground and in the water which had dropped from the above conveyors into the drainage ditch. The firm does not have an SOP for cleaning up the manure which drops from the manure conveyors into the drainage ditch.

See Exhibit #16 – Two (2) pictures of the (b) (4) elevated manure conveyors over the drainage ditch which transport dry manure from the poultry houses into the manure building; Picture files: Cal-Maine 030911 1152.jpg and Cal-Maine 30911 1204-2.jpg (2 pages)

- The wheelbarrows travel down an approximate 5' embankment, across 1 of 2 metal grates (~10' long x 2' wide with 3/4" holes lying in the wet sand and water) in a drainage ditch, and up an approximate 5' embankment. Bird tracks were observed adjacent to the metal grate. Birds were also observed on the ground underneath the manure conveyor belts. Wild birds are a potential source of Salmonella Enteritidis (SE).

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See Exhibit #17 – Two (2) pictures of the drainage ditch, metal crossing and adjacent bird tracks; Picture files: Cal-Maine 030911 1152-2.jpg and Cal-Maine 030911 1208.jpg (2 pages)

- The wheelbarrows travel across a dirt parking lot to the (b) (4) mortality shed. The dirt parking lot is ~100'; a picture of the dirt parking lot was not taken.

See Exhibit # 18– Picture of the inside of the refrigerated mortality shed; Picture file: Cal-Maine 030911 1209.jpg

- Cal-Main Foods, Inc. Biosecurity Program states in part:

Section F. Dead Birds Exhibit 7 Page #4 states:

1. "Dead birds will be picked up daily and removed from the houses."
2. "Dead birds will be disposed of properly and humanely."

Boot Dipping Procedures Exhibit 7 Page #31) states in part:

"Procedures for using boot dip station

When employees return from the mortality shed or manure barns they must walk around the layer or pullet houses and enter using the foot bath."

Daily Operating Procedures for SE Negative Environment (Exhibit 7 Page #51) states:

"Cal-Main Foods, Farwell, TX policy during SE negative conditions will be as follows:

All flocks will be treated as one flock and employees will be allowed to travel from house to house throughout the day to perform their work assignments. All tools and equipment needed to perform assignments will be permitted to be used in all houses. This includes but is not limited to cleaning tools as well as maintenance tools and machinery."

- The wheelbarrows cross the drainage ditch over two metal grates. The front rubber tires of the wheelbarrows make contact with the dirt, the metal grate, the wet sand and the water. Wild birds adjacent to the metal grates and underneath the manure conveyors are a potential source of Salmonella Enteritidis (SE). The firm does not have an SOP in the Cal-Main Foods, Inc. Biosecurity program for the cleaning and sanitizing of the wheelbarrows prior to re-entering the (b) (4) Poultry Houses #LC through LC (b) (4)

See Exhibit 19 – One (1) Officially Sealed CD-ROM with 85 digital picture files; Picture files: Cal-Maine 030811 240.jpg – Cal-Maine 031111 1012-2 (labeled with date and time)

The CD-ROM picture files are identified as follows:

- Layer House LC# - 3/8/2011
Picture files: Cal-Maine 030811 240.jpg - Cal-Maine 030811 405-3.jpg

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-
- Layer House LC# [REDACTED] - 3/9/2011
Picture files: Cal-Maine 030911 939.jpg - Cal-Maine 030911 1140.jpg
 - Drainage ditch, manure conveyors, manure building, mortality shed, wheelbarrows and metal crates - 3/9/2011
Picture files: Cal-Maine 030911 1149.jpg - Cal-Maine 030911 1209.jpg
 - Water Evaporation Lagoon - 3/9/2011
Picture file: Cal-Maine 030911 1212.jpg
 - Layer House LC# [REDACTED] - 3/9/2011
Picture files: Cal-Maine 030911 227.jpg - Cal-Maine 030911 337.jpg
 - Layer House LC# [REDACTED] - 3/10/2011
Picture files: Cal-Maine 031011 257.jpg - Cal-Maine 031011 305-2.jpg
 - Boot Dip Station - Employee Entrance - 3/10/2011
Picture file: Cal-Maine 031011 337.jpg
 - Egg Processing and Packing Room - 3/10/2011
Picture file: Cal-Maine 031111 1005.jpg
 - Egg Cooler - 3/10/2011
Picture files: Cal-Maine 031111 1012.jpg - Cal-Maine 031111 1012-2.jpg

Discussion with Management:

On 3/11/2011, Mr. Michael A. Gibson, General Manager stated that on 3/10/2011 he had instructed employees not to bring the mortality wheelbarrows into the layer houses. Mr. Gibson stated that the firm would respond to FDA in writing regarding this observation within fourteen (14) business days.

REFUSALS

There were no refusals during the inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Present at the firm were Mr. Michael A. Gibson, General Manager and Mr. Robert "Bob" Burger, Production Manager.

Discussion Item #1: Three exterior doors were observed which would not close when opened unless pushed closed due to the cylinders not retracting. Two doors were observed with damaged bottom rubber seals.

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Mr. Michael A. Gibson, General Manager stated that a locksmith had been contacted and that the doors should be repaired within one week. He stated that the bottom seals were a (b) (4) training issue which would be reinforced with employees.

Discussion Item #2: Exterior pipes from the feed hoppers had degraded seals when they entered the exterior layer house walls.

Mr. Bob Burger, Production Manager stated that the seals would be repaired within 1-2 weeks or as soon as replacement parts could be ordered and received.

Discussion Item #3: Concerned employees exiting and entering the layer houses and not going through the foot bath.

Mr. Michael A. Gibson, General Manager stated that the firm would consider some form of disinfectant spray for employees to use when they re-entered the layer houses from outside.

There were no other discussion items. We asked if there were any further questions, there were no further questions, we thanked Mr. Gibson and Mr. Burger for their cooperation, and the inspection was closed.

ADDITIONAL INFORMATION

The following checklist is inserted in this EIR as directed in **FACTS assignment # 1209037**, Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFIG Assignment # 10-29, ORA Concurrence # 2010092001, dated 09/20/2010:

**ATTACHMENT B: INSPECTION/DATA COLLECTION TOOL FOR
COMPREHENSIVE INSPECTIONS**

Information that needs to be obtained in addition to the general FDA information

Section I: Information for assessing future inspectional priority)

| <u>Question</u> | <u>Criteria</u> |
|--|--|
| What is the firm's compliance history? | No inspection history |
| Is there evidence of public health concerns? | No evidence of public health concern |
| Has the firm had an order of diversion? | The firm has not had to order a diversion. |
| Does the firm participate in any certification | Yes, the participates in 3 rd party audits: |

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| | |
|---|--|
| programs? | (b) (4) |
| What are the farm practices? | Caged |
| What is the production volume? | Number of laying hens is (b) (4) Number of eggs produced (b) (4) cases per week (b) (4) eggs per case. The firm's Gross annual sales in approximately (b) (4) a year |
| In what type of market will eggs be sold? | Shell egg market |
| <u>Diversion Metrics:</u> If a firm has ever diverted eggs, document the following items in the EIR: *The firm has never diverted eggs* | <ul style="list-style-type: none"> • What triggered the diversion: environmental sample positive and/or product test • How many eggs were diverted • Time period (days, months etc) of diversion • Source receiving the diverted eggs (breaker, etc) • When and why diversion ended |

Section II: Inspectional Tool (*NR = No Reference for the observation in Egg Safety Regulation, but information will be useful for risk assessment to determine which firms to subsequently reinspect.)

| Inspectional Information | Section of Egg Rule - Reference |
|--|---------------------------------|
| General | |
| Is the farm registered according to the Egg Rule? Yes, as described in the section of this report titled Manufacturing / Design Operations | 118.11 (specifically 118.1) |
| Determine the owner of the birds (not the owner of the poultry house). | * N.R. |
| Cal-Maine Foods Inc. is the owner of the birds, poultry houses, and pullets. | |
| Determine who packs the eggs. | * N.R. |
| Cal-Maine Foods Inc. has an egg plant on site. USDA monitored shell egg plant and located onsite. | |
| What is the plant 'P' number? P2-007 | * N.R. |
| Are all eggs dedicated to a 5 log treatment or delivered to an egg products plant? The firm has never had a positive environmental sample so the firm has not had to dedicate eggs to a 5 log treatment plant. | 118.1 records 118.10 |

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| <u>Inspectional Information</u> | <u>Section of Egg Rule - Reference</u> |
|--|---|
| What is the name and where is the egg products plant? Cal-Maine Foods Inc. has an egg plant on site. USDA monitored shell egg plant and located onsite. | * N.R. |
| Is this a breaking plant only or breaking/treatment plant? NO | * N.R. |
| What is the 5 log treatment process and where is it being done? N/A | * N.R. |
| Egg Farm Plan (118.4) | |
| Does a written plan exist for each site? YES | 118.10 |
| Obtain a copy of the plan. A copy of the plan can be seen at Exhibit | * N.R. |
| If all the eggs go to a treatment plant, skip to the refrigeration questions. | |
| Is there a designated administrator for the plan and what training has the person obtained? Yes, The on-site plan administrator is the General Manager at the firm. The plan was signed by Ryn Laster McDonald, Ph.D. on 10/04/2010 and Michael Gibson, General Manager on 10/06/2010. | 118.9 |
| Does the plan cover the following: | 118.4 |
| -Biosecurity YES | 118.4 |
| -Chick supplier YES | 118.4 |
| -Pullet rearing as SE monitored YES | 118.4 |
| -Pest control program for flies, rodents, and others YES | 118.4 |
| -Cleaning and Disinfection (C & D) procedure YES | 118.4 |
| -Environmental sampling and testing procedure YES | 118.4 for pullets and 118.5 for laying hens |
| -Environmental testing interval YES | 118.4 for pullets and 118.5 for laying hens |
| -Diversion of eggs procedure | 118.6 |
| -Sampling and testing of eggs procedure YES | 118.8 |
| -Refrigeration YES | 118.4 |
| Is there any paperwork/records/ documentation for the following? Yes the firm provided all paper work for the following sections. | 118.10 |

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| <u>Inspectional Information</u> | <u>Section of Egg Rule - Reference</u> |
|--|--|
| Egg Farm Plan (110.4) cont'd | |
| -Chicks YES, see manufacturing section of this report for further information | 118.10 |
| -Pullet rearing SE monitored document YES, the firm provided documentation for SE monitored pullets | 118.10 |
| -Environmental sampling procedure and testing procedure. Yes | 118.10 |
| -Testing results for environmental sampling Yes | 118.10 |
| -Egg sampling procedure and testing procedure YES | 118.10 |
| -Test results for egg sampling YES | 118.10 |
| -Diversion of eggs. The firm has a written plan for diversion. However the firm has never had to divert eggs | 118.10 |
| -C & D procedures and documents. Yes the firm has a written procedure | 118.10 |
| -Biosecurity Yes the firm has a written procedure | 118.10 |
| -Rodent/pest control Yes the firm has a written procedure | 118.10 |
| -Refrigeration Yes the firm has a written procedure | 118.10 |
| -Review of plan and changes. If the plan is changed it will be sign by upper management and will be added to the current S.E. plan | 118.9 |
| Flock Information (per house) | |
| Who is the supplier of the chicks? Cal-Maine Foods, Inc. supplies chicks from their hatcheries | * N.R. |
| Where were the pullets reared? On-Site the firm has (b) (4) house dedicated for pullets. | * N.R. |
| Is the flock an organic flock? NO | * N.R. |
| How many houses are on the site? (b) (4) layer houses and (b) (4) pullet houses | * N.R. |
| How does the farm designate the houses? The firm designates the houses by ages of the flock. See manufacturing design section for more information | * N.R. |
| Per house on the site: | |
| -What is the strain of bird? (b) (4) | * N.R. |
| -What is the age of the birds? Refer to section of this report titled Manufacturing / Design Operations | * N.R. |
| -What is the number of birds in the house and per cage? (b) (4) birds per cage | * N.R. |
| Are the houses stocked with birds as an 'all in, all out' procedure? Yes | * N.R. |
| House Design (per house) | |

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| <u>Inspectional Information</u> | <u>Section of Egg Rule - Reference</u> |
|--|--|
| What types of houses are on the site? (b) (4) Houses that are (b) (4) operated | * N.R. |
| If the houses use cages, what is the configuration – rows, tiers? Rows with a total of tiers per row | * N.R. |
| If the house has no cages, how is it configured for nesting boxes and egg collections? N/A | * N.R. |
| Are there any divisions in the house? N/A | * N.R. |
| How is the manure handled per house? The houses have manure belts that transport the manure out of the house. The belts are ran a week. | * N.R. |
| Feed and Water (per house) | |
| Who is the feed supplier? The firm has their own feed mill located on-site | * N.R. |
| What are the ingredients of the feed? A formulation sheet can be seen for the feed ingredients at Exhibit 10 | * N.R. |
| -Corn Yes | * N.R. |
| -Soybean Yes | * N.R. |
| -Minerals Yes | * N.R. |
| -Animal protein NO | * N.R. |
| -CA source (lime stone) | * N.R. |
| -Vitamins Yes | * N.R. |
| -Discarded bakery products No | * N.R. |
| -Least cost | * N.R. |
| What kind of feed system is being used- auger, chain, other? Auger | * N.R. |
| What kind of watering system is being used- nipple, cup, other? Nipple | * N.R. |
| Is the water source a well or municipal system? Well Water | * N.R. |
| Is the water chlorinated or tested for microorganism? Yes, the well water is tested (b) (4) a year. The firm provided documentation of the tests. The test analysis of the firm's well showed the wells chloroform free. | * N.R. |
| Biosecurity Measures (per house) 118.4 | |
| What measures are observed? See manufacturing design section for more information | 118.4 |
| Do they include any of the following? | |

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| <u>Inspectional Information</u> | <u>Section of Egg Rule - Reference</u> | | | | | | | | | | | | | | | | | | | | | | |
|--|--|----------|-------|----------------------|-------|---|-------|----------------------------|-------|----------------------------|-------|---|-------|--|-------|--|-------|---|-------|--|-------|--|-------|
| -Perimeter fencing Yes | *NR | | | | | | | | | | | | | | | | | | | | | | |
| -Gates | *NR | | | | | | | | | | | | | | | | | | | | | | |
| -Footbaths Yes | *NR | | | | | | | | | | | | | | | | | | | | | | |
| -Special or limited clothing or shoes NO | *NR | | | | | | | | | | | | | | | | | | | | | | |
| -Limitation of equipment sharing between houses. No See manufacturing design section for more information | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Visitor restrictions Yes | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| What non-poultry animals are observed in the poultry houses? Non observed | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| Are there any rodent feces, skeletons, gnaw holes or non-poultry bird feather? No | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| In which houses were the animals observed? N/A | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| Pest Control (per house) 118.4 <table border="1"> <tr> <td>Rodents:</td><td>118.4</td></tr> <tr> <td>-Traps/bait stations</td><td>118.4</td></tr> <tr> <td>-Are they inside and/or outside of the house? Bait stations and (b) (4) (hinged-door live traps) are located outside of the firm. (b) (4) outside of the firm are used for monitoring purposes. (b) (4) are located inside of the firm.</td><td>118.4</td></tr> <tr> <td>-Are they functional? Yes.</td><td>118.4</td></tr> <tr> <td>-Are they accessible? Yes.</td><td>118.4</td></tr> <tr> <td>-Is bait present? Yes; firm uses the (b) (4) with (b) (4) and (b) (4)</td><td>118.4</td></tr> <tr> <td>-Are there dead rodents, decaying or skeleton present? None were observed.</td><td>118.4</td></tr> <tr> <td>-Is there nesting material? None was observed.</td><td>118.4</td></tr> <tr> <td>-Is there loose bait/ blocks present? None were observed.</td><td>118.4</td></tr> <tr> <td>-Were live rodents observed? None were observed.</td><td>118.4</td></tr> <tr> <td>-Is the monitoring program in the plan</td><td>118.4</td></tr> </table> | | Rodents: | 118.4 | -Traps/bait stations | 118.4 | -Are they inside and/or outside of the house? Bait stations and (b) (4) (hinged-door live traps) are located outside of the firm. (b) (4) outside of the firm are used for monitoring purposes. (b) (4) are located inside of the firm. | 118.4 | -Are they functional? Yes. | 118.4 | -Are they accessible? Yes. | 118.4 | -Is bait present? Yes; firm uses the (b) (4) with (b) (4) and (b) (4) | 118.4 | -Are there dead rodents, decaying or skeleton present? None were observed. | 118.4 | -Is there nesting material? None was observed. | 118.4 | -Is there loose bait/ blocks present? None were observed. | 118.4 | -Were live rodents observed? None were observed. | 118.4 | -Is the monitoring program in the plan | 118.4 |
| Rodents: | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Traps/bait stations | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Are they inside and/or outside of the house? Bait stations and (b) (4) (hinged-door live traps) are located outside of the firm. (b) (4) outside of the firm are used for monitoring purposes. (b) (4) are located inside of the firm. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Are they functional? Yes. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Are they accessible? Yes. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Is bait present? Yes; firm uses the (b) (4) with (b) (4) and (b) (4) | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Are there dead rodents, decaying or skeleton present? None were observed. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Is there nesting material? None was observed. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Is there loose bait/ blocks present? None were observed. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Were live rodents observed? None were observed. | 118.4 | | | | | | | | | | | | | | | | | | | | | | |
| -Is the monitoring program in the plan | 118.4 | | | | | | | | | | | | | | | | | | | | | | |

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|---|-------|--|
| being followed? Yes. | | |
| Fly: | 118.4 | |
| -What is the control measure (chemical, mechanical or other?) (b) (4) Granular Fly Bait and sticky traps for monitoring. | 118.4 | |
| -If chemical, what is the spray or bait being used? (b) (4) bait (b) (4) and (b) (4) attractant) and spray (b) (4) | *NR | |
| -What is the schedule for usage? (b) (4) to (b) (4) as needed. | 118.4 | |
| -If mechanical, what is the mechanism used? N/A; Light traps are only used in the corporate offices. | 118.4 | |
| -If electrical, what is the mechanism? N/A | 118.4 | |
| -What monitoring was observed and is that per the program? Moving sticky trap (tape) method. Yes (Biosecurity SE Plan; Page #40). | 118.4 | |
| Rodents: | 118.4 | |
| -Traps/bait stations Yes | 118.4 | |
| -Are they inside and/or outside of the house? Yes, see pest control section of this report for further information | 118.4 | |
| -Are they functional? Yes | 118.4 | |
| -Are they accessible? Yes | 118.4 | |
| -Is bait present? Yes | 118.4 | |
| -Are there dead rodents, decaying or skeleton present? NO | 118.4 | |
| -Is there nesting material? NO | 118.4 | |
| -Is there loose bait/ blocks present? NO | 118.4 | |
| -Were live rodents observed? NO | 118.4 | |
| -Is the monitoring program in the plan being followed? Yes | 118.4 | |
| Fly: | 118.4 | |
| -What is the control measure (chemical, mechanical or other?) | 118.4 | |
| -If chemical, what is the spray or bait being used? | *NR | |
| -What is the schedule for usage? | 118.4 | |

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|---|--|
| -If mechanical, what is the mechanism used? | 118.4 |
| -If electrical, what is the mechanism? | 118.4 |
| Manure Management | |
| If the poultry house has pits, how often and how much of the manure is removed? NO | * N.R. |
| What is the condition of the manure (dry, wet)? Dry | * N.R. |
| Are rodent burrows observed? No | * N.R. |
| If the house uses either belts or scraper, how often are these run? Belts are ran once a week | * N.R. |
| If the house uses a flush system, how often is this run? No | * N.R. |
| Cleaning and Disinfection (C & D) 118.4 | |
| Any reported SE positive houses needing C & D? NO | 118.4 |
| Any procedures observed? Yes firm has written C&D Procedures | 118.4 |
| What are the procedures for environmentally SE positive versus environmentally SE negative houses? | 118.4 |
| See Manufacturing Section of the report for further information | |
| Environmental Verification Testing 118.5 | |
| Have any samples been obtained? YES | 118.5 |
| Were samples obtained at appropriate times? YES | 118.5 |
| Any positive results and if so, what did the firm do? NO Positives | 118.5 |
| Egg Testing 118.6 | |
| If environmental SE positive houses were found, were the eggs diverted or tested? N/A | 118.6 |
| If eggs were tested, where, when, and what were the results? N/A | 118.6 |
| Refrigeration 118.4 | |
| Are eggs processed within 36 hours? YES | 118.4 |
| If eggs are held >36 hours, at what temperature are they held and how is this temperature monitored? See Refrigeration section of this report for further information | |

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|---|--|
| | 118.4 |
| How is the temperature monitored in the transport vehicle if the eggs are held longer than 36 hours? See Refrigeration section of this report for further information | 118.4 |
| Any additional information or details given or observations should be noted. | |

A response in writing to the FDA 483 and pictures from Ruben Acevedo, Compliance Manager was received by fax on April, 1 2011. The fax can be seen as **Exhibit 20 pages 1-2**. Ms. Carolyn Elkins, Office Automation Assistant received the fax and hand delivered the response letter to Ricky Rodriquez on 04/01/2011.

SAMPLES COLLECTED

Written by Paul E. Frazier

Four samples were collected during the establishment inspection. The four samples consisted of environmental swabs. The samples were collected in accordance with the Amended Assignment – FY 11—Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule, DFIG Assignment # 11-04, ORA Concurrence # 2011012601 Facts No. 1258067. The samples were collected from the (b) (4) poultry houses to assess conditions and obtain baseline information about the state of the industry. Each house sampled was a (b) (4) house. Each house contained (b) (4) floors. Each floor contained rows with tiers that each contained a scraper blade and a manure belt. The samples were analyzed for Salmonella Enteritidis (SE). All samples were negative for Salmonella Enteritidis (SE). A FDA 484, Receipt for Samples was issued to Mr. Gibson on 3/11/2011 for all four samples. To view Receipt for samples see **Attachment 3**. The following samples were collected:

1. Sample #INV648673 was collected on 3/8/2011. The sample was collected from hen Layer Complex (LC) (b) (4). The hens in LC (b) (4) were 26 weeks old. The sample consisted of 28 environmental swabs taken from the area around the scraper blades of tiers (b) (4) of the (b) (4) house. Included with sample INV648673 were closed controls of materials used to conduct sampling; FACTS #1258067, OP ID #5311896.
2. Sample #INV648672 was collected on 3/9/2011. The sample was collected from hen Layer Complex (LC) (b) (4). The hens in LC (b) (4) were 34 weeks old. The sample consisted of 28 environmental swabs taken from the area around the scraper blades of tiers (b) (4) of the (b) (4) house. Controls for these environmental samples were sent with Sample INV648673; FACTS #1258067, OP ID #5257389.

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3. Sample #INV604287 was collected on 3/9/2011. The sample was collected from hen Layer Complex (b) (4) LC (b) (4). The hens in LC (b) (4) were 74 weeks old. The sample consisted of 28 environmental swabs taken from the area around the scraper blades of tiers (b) (4) of the (b) (4) house. Controls for these environmental samples were sent with Sample INV648673; FACTS #1258067, OP ID #5312013.
4. Sample #INV604288 was collected on 3/10/2011. The sample was collected from hen Layer Complex (b) (4) LC (b) (4). The hens in LC (b) (4) were 102 weeks old. The sample consisted of 28 environmental swabs taken from the area around the scraper blades of tiers (b) (4) of the (b) (4) house. Controls for these environmental samples were sent with Sample INV648673; FACTS #1258067, OP ID #5312014.

EXHIBITS COLLECTED

- Exhibit 1** – Cal-Maine Foods, Inc. Document # 24004745, dated 02/18/2011 showing sales including cases shipped to (b) (4) (1 page)
- Exhibit 2** – Cal-Maine Foods, Inc. Document #24004808, dated 02/26/2011 showing sales including cases shipped to (b) (4) (1 page)
- Exhibit 3** – Cal-Maine Foods, Inc Document # 24004746, dated 02/18/2011 showing sales including cases shipped to (b) (4) (1 page)
- Exhibit 4** – Copy of Cal-Maine Foods, Inc. Organizational Chart showing all firm operations reporting to Mr. Michael A. Gibson, General Manager. (1 Page)
- Exhibit 5** – Copy of Cal-Maine Foods, Inc. Organizational Chart of the entire company. (1 page)
- Exhibit 6** – Copy of Cal-Maine Foods, Inc. showing that the plan was signed by signed by Ryn Laster McDonald, Ph.D., Director of Food Safety on 10/04/2010 and Michael A. Gibson, General Manager on 10/06/2010.
- Exhibit 7** – Copy of Cal-Maine Foods, Inc. SE Prevention Plan (57 Pages)
- Exhibit 8** – Photographs showing the general setting and conditions of the Cal-Maine Foods, Inc. (5 pages)
- Exhibit 9** – Copy of the status report showing number of hens, age of hens, and temperature of each house (1 page)
- Exhibit 10** – Copy of feed ingredients formulation sheet (1 page)
- Exhibit 11** – National Poultry Improvement Plan (NPIP) Report # Y073189, Report of Sales of Hatching Eggs, Chicks, and Poults (pullets) showing that (b) (4) variety poults (pullets) from the load were sold to Cal-Maine Farms, Farwell, TX on 8-31-2010 2 pages.
- Exhibit 12** – Environmental Sampling log with results (14 pages)
- Exhibit 13** – SOP for Manure Belt Poultry House sampling (2 pages)
- Exhibit 14** – Photographs of wheelbarrows used to store and transport mortality layers from the (b) (4) layer houses to the mortality shed (4 pages)

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Exhibit 15 – Photographs of the dirt road and drainage ditch the wheelbarrows cross to travel from the (b) (4) layer houses to the mortality shed. (2 pages)

Exhibit 16 – Photographs of the (b) (4) elevated manure conveyors over the drainage ditch which transport dry manure from the poultry houses into the manure building. (2 pages)

Exhibit 17 – Two (2) pictures of the drainage ditch, metal crossing and adjacent bird tracks

Exhibit 18 – Picture of the inside of the refrigerated mortality shed (1 page)

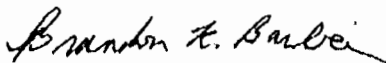
Exhibit 19 – Package Identification containing officially sealed CD-ROM containing photos taken during the inspection. (1 page)

ATTACHMENTS

Attachment #1 – Form FDA 482, Notice of Inspection, dated 03/08/2011

Attachment #2 – Copy of Form FDA 483, Inspectional Observations, dated 03/11/2011 (1 pg.)

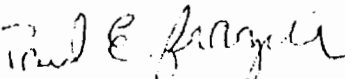
Attachment #3 – Form FDA 484, Receipt for Samples dated 3/11/2011 for Samples #INV648672, INV648673, INV604287 and INV604288 (1 pg.)



Brandon K. Barbee, Investigator



Grant L. Davis, Investigator



Paul E. Frazier, Investigator